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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,183	05/18/2007	Hiroyuki Tsunoda	14875-162US1 C1-A0311P-US	1638

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

NOTIFICATION DATE	DELIVERY MODE
08/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,183	TSUNODA ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *21 and 23-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/27/2007;10/19/2007;7/31/2008;6/30/2009;7/28/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of June 2, 2009, to the Restriction Requirement dated March 2, 2009 has been entered. No claims have been amended, cancelled, or newly added. Accordingly, claims 1-39 remain pending in the application.

Election/Restrictions

Applicant's election of Group I (claims 1-20 and 22) drawn to a DNA construct wherein a mammalian β-actin promoter is operably linked to an enhancer; a vector comprising said construct, and a cell comprising said vector, is acknowledged. The election has been made without traverse. Applicants' election for the species of mouse β-actin promoter, CMV enhancer, mouse c-H-ras transactivator/oncogene and hamster cell, is further acknowledged. Accordingly, claims 3, 6, 20, 21 and 23-39 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and non-elected species of the invention, there being no allowable generic or linking claim.

As the requirement for restriction is deemed proper, it is maintained and hereby made **FINAL**. Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

The instant claims have been examined commensurate with the scope of the elected species of the invention. Applicants timely responded to the restriction (election) requirement in the reply filed June 4, 2009.

Claims 1, 2, 4, 5, 7-19 and 22 are under current examination

Information Disclosure Statement

The information disclosure statements (IDS) submitted on July 27, 2007, October 19, 2007, July 31, 2008, June 30, 2009 and July 28, 2009 are in compliance with the provisions of 37

CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner, and indicated as such on Applicants' IDS forms.

Objection to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Further, an incorporation by reference by hyperlink or other form of browser executable code is not permitted. See 37 CFR 1.57(d) and MPEP § 608.01. The attempt to incorporate subject matter into this application by reference to a website (Examples 1 and 3), is ineffective because the nature of websites is transitory. Neither applicants nor the USPTO has any control on the content and availability of the information referred to at the website above. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier. Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 14 recite the limitations "the oncogene" and “the transactivator” in the second lines of the claims. There is insufficient antecedent basis for these limitations in the claims. Claim 16 depends from claim 14, and has thus been included in the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 7, 8, 12, 13, 17-19 and 22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hadjantonakis et al. (Mech. Develop. 76:79-90, 1998), in view of Estes et al. (U.S. Patent No.: 7,423,135; effective filing date Jun. 24, 2003).

The claims embrace a DNA construct wherein a mouse β-actin promoter is operably linked to a CMV enhancer; a vector comprising said construct, and a hamster cell comprising said vector.

Hadjantonakis et al. describe the generation of transgenic mice expressing a GFP marker transgene, wherein the GFP expressing vector drives marker expression by a CMV immediate early enhancer coupled to a the chicken β-actin promoter (Abstract; second columns, p. 80 and 88 limitation of claims 1, 2, 7, 8 and 12). The authors further describe the establishment of ES

cell lines by transformation via electroporation, with the vector (first column, p. 80; limitation of claim 22).

While Hadjantonakis et al. do not describe their β-actin promoter as obtained from a mouse, such was known in the prior art.

Estes et al. disclose rodent promoters, including that of hamster and mouse (Abstract), further providing vectors comprising the promoters for expressing heterologous genes of interest in hamster cells such as CHO, HEK and BHK (column 2, lines 9-20; limitation of claims 4, 13 and 17-19). Estes et al. further disclose the nucleotide sequence of the mouse β-actin promoter as SEQ ID NO: 3, and state that the chicken β-actin promoter has been shown to exhibit a higher activity than viral CMV and SV40 promoters, but only when it is linked to a CMV enhancer (column 1, lines 42-45), thus providing the motivation to link a CMV enhancer to other β-actin promoters.

The teachings of Hadjantonakis et al. and Estes et al. are both directed to the expression of genes of interest under the control of β-actin promoters. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine their respective teachings and to substitute the mouse β-actin promoter for the chicken β-actin promoter with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would construct such an expression construct in an expression vector as a matter of design choice, which amounts to simple substitution of one known element for another to obtain predictable results. Applicants should note that the *KSR* case forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR International Co. v. Teleflex Inc.*, 550 U.S.-, 82USPQ2d 1385 (2007).

Claims 1, 2 and 5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Estes et al. (U.S. Patent No.: 7,423,135; effective filing date Jun. 24, 2003), and further in view of Debs et al. (U.S. Patent No.: 6,468,798; filed Jan. 14, 1998).

The claims embrace a DNA construct wherein a mouse β-actin promoter comprising SEQ ID NO: 2 is operably linked to a CMV enhancer comprising SEQ ID NO: 4

Estes et al. disclose rodent promoters, including that of hamster and mouse (Abstract), further providing vectors comprising the promoters for expressing heterologous genes of interest. Estes et al. further disclose the nucleotide sequence of the mouse β-actin promoter as SEQ ID NO: 3 (wherein nucleotides 1413-2593 correspond to instant SEQ ID NO: 2), and state that the chicken β-actin promoter has been shown to exhibit a higher activity than viral CMV and SV40 promoters, but only when it is linked to a CMV enhancer (column 1, lines 42-45), thus providing the motivation to link a CMV enhancer to other β-actin promoters.

While Estes et al. do not disclose the nucleotide sequence of the CMV enhancer as SEQ ID NO: 4, such was known in the prior art.

Debs et al. disclose the sequence of the hCMV enhancer as nucleotides 156-521 of SEQ ID NO: 4 and state: "The combination of promoter and enhancer elements used in a particular expression cassette can be selected by one skilled in the art to maximize specific effects (column 8, lines 12-15).

The teachings of Estes et al. and Debs et al. both include the utilization of CMV enhancer with promoters. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine their respective teachings and to use nucleotides disclosed in SEQ ID NO: 4 corresponding to the CMV enhancer in combination with the mouse β-actin promoter with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would construct such an expression construct in an expression vector as a matter of design choice, to obtain an expression construct having higher expression levels than using the promoter alone.

Claims 1, 7-11 and 14-16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Estes et al. (U.S. Patent No.: 7,423,135; effective filing date Jun. 24, 2003), in view of Yano et al. (Cytotech. 16:167-178; 1994; of record) and further in view of GenBank BC011083 (2002).

The claims embrace a DNA construct wherein a mouse β-actin promoter is operably linked to a CMV enhancer; a vector comprising said construct and a mouse c-Ha-ras oncogene, and a hamster cell comprising said vector.

Estes et al. disclose rodent promoters, including that of hamster and mouse (Abstract), further providing vectors comprising the promoters for expressing heterologous genes of interest. Estes et al. state that the chicken β-actin promoter has been shown to exhibit a higher activity than viral CMV and SV40 promoters, but only when it is linked to a CMV enhancer (column 1, lines 42-45), thus providing the motivation to link a CMV enhancer to other β-actin promoters.

While Estes et al. do not disclose the inclusion of a c-Ha-ras oncogene in their CMV/ β-actin vectors, such was known in the prior art.

Yano et al. describe the c-Ha-ras oncogene as capable of enhancing promoter activity when expressed downstream of the CMV promoter and transactivating β-actin in BHK-21 cells (Title and Abstract), thus providing the motivation to include said oncogene in the vector of Estes et al. The mouse c-Ha-ras gene was known in the prior art as evidenced by GenBank BC011083.

The teachings of Estes et al. and Yano et al. both include the utilization of CMV promoter elements to increase transcription via vector constructs. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine their respective teachings and to include the human or mouse c-Ha-ras oncogene in the vector of Estes et al. with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would produce such an expression construct in an expression vector to increase promoter activity, and because such was expressly taught by Yano et al.

Conclusion

Claims 1, 2, 4, 5, 7-19 and 22 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/
Primary Examiner, Art Unit 1633